Corrective Actions: When it all goes wrong…Getting to Correctness

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Objectives

- Where do we start when it all goes wrong
- Who, What, Where, When, Why & How
- What to do with the Final Answer

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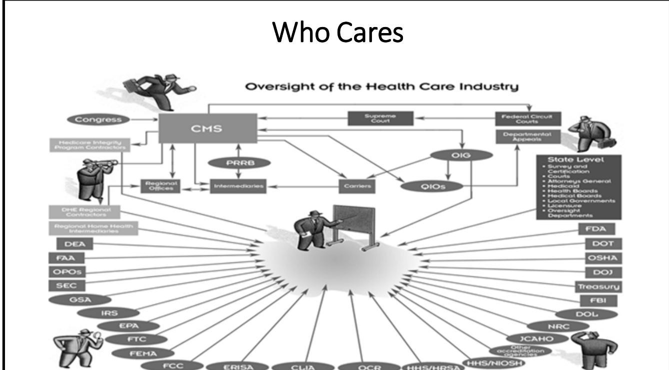
Who Cares



Why

U.S. Department of Justice
Evaluation of Corporate Compliance Programs

- **Analysis and Remediation of Underlying Misconduct**
- **Root Cause Analysis** – What is the company's root cause analysis of the misconduct at issue? What systemic issues were identified? Who in the company was involved in making the analysis?
- **Prior Indications** – Were there prior opportunities to detect the misconduct in question, such as audit reports identifying relevant control failures or allegations, complaints, or investigations involving similar issues? What is the company's analysis of why such opportunities were missed?
- **Remediation** – What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future? What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?

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What

Root cause analysis (**RCA**)
is a method of problem solving used for identifying the root causes of faults or problems. A factor is considered a root cause if **removal** thereof from the problem-fault-sequence **prevents** the final **undesirable event from recurring**; **whereas a causal factor is one that affects an event's outcome, but is not a root cause.** Though removing a causal factor can benefit an outcome, it does not prevent its recurrence with certainty.

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Investigation (fact finding)

VS.

RCA (cause)

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Process

- **Who** **Why**
- **What** **Why**
- **Where** **Why**
- **When** **Why**
- **Why** **Why**
- **How** **Why**

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RCA STEPS

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Charter

- What is an RCA?
- What is the role of the RCA team?
- Who is on the Base Team?
- Process for identifying additional team members?
- What is the size of the team?
- How to determine facilitator?

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Base Team

- Compliance
- Risk Management
- Legal Counsel (attorney client privilege)
- Quality
- Administration Representative
- Chief Medical Officer

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Select the event to be investigated and gather preliminary information

- Gather documents (investigation report, hotline, policies, ect.)
- Start with problem not solution
- What went wrong not why or how
- Focus on process/system

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Select team facilitator and team members

- Base team
- Charter
  - review with full team
- Identify facilitator
- Members determined by problem (personal knowledge of the problem)

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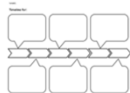
Describe what happened

- Time line of events
  - *does time line tell the story*
  - *Is each step pertinent to the event*
  - *Was a step left out*



- Resist skipping steps

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Identify the contributing factors

- Review each step in the timeline
  - What was going on that increased the likelihood
- Brainstorming an effective tool
- Avoid hindsight
  - Factor present and known

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Identify the root causes

- All incidents have a direct cause
- Cause versus contributing factor
- Ask
  - would the event have occurred if this cause had not been present
  - Will the problem recur if this cause is corrected or eliminated
- Don’t judge individual
- Frank and open discussion of cause and event

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Design and implement changes to eliminate the root causes

- Evaluate each root cause
  - choose action to address root cause
    - process/system

- Short term solutions
  - fix contributing factor
  - rarely fix the cause

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Measure the success of changes

- Did corrective action get implemented
- Are people complying with changes
- Have changes made a difference
- Measure over time
- Confident change is permanent

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Corrective Actions

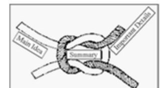
Root Cause	Corrective Action	Responsible Individual/Group	Completion Deadline

Measure of Success

Corrective Action	Measure of Success (How will we know if this action is successful)	Reporting Schedule

Summary

- Selective in events for RCA
- Base team vs. RCA team
- Timeline of event
- Root causes
- Corrective actions
- Measuring success (auditing/monitoring)
- Why, Why, Why, Why, Why, etc.



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Questions

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